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September 10, 2012

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, D.C. 20201

Dear Secretary Sebelius:

As you are probably aware, on August 22, 2012, the National Institutes of Health (NIH) announced in a press release the occurrence of a deadly outbreak of a multi-antibiotic-resistant Klebsiella at its Clinical Center that started in June 2011 and lasted until at least December 2011.[1] Of note, the timing of the belated NIH announcement was not determined by any public health considerations or the need to inform the public about this dangerous public health threat, but rather by the desire to give itself a self-congratulatory pat on the back coincident with the publication of a scientific paper in the online edition of *Science Translational Medicine* describing how NIH scientists used sophisticated bacterial genome sequencing techniques to track the spread of the infection from patient to patient.[2]

However, information provided in the published scientific paper and the related NIH press release, as well as statements made by NIH officials in several media reports, raises numerous troubling, unanswered questions about the NIH's handling of information related to this outbreak and the research agency's failure to promptly inform all potentially affected patients, public health authorities, and the public at large.

Public Citizen therefore strongly urges you to initiate an independent investigation of this matter. Some of the key problems, relevant evidence, and pertinent questions that need to be addressed in such an inquiry are the following:

(1) The serious threat that the multi-drug-resistant Klebsiella outbreak posed to patients starting in the summer of 2011 is clearly evidenced by the extraordinary measures implemented by the Clinical Center to combat the outbreak, the mortality rate associated with these infections, and the numerous statements made by the NIH in its August 22 press release and in statements to the media.

For example, the NIH press release included the following statements: [3]

> For six months last year, a **deadly outbreak** of antibiotic-resistant bacteria kept infection-control specialists at the National Institutes of Health's Clinical Center **in a state of high alert** [emphasis added]. …

> Despite enhanced infection-control practices, including patient isolation, **the K. pneumoniae began to spread to other Clinical Center patients at the alarming rate of one a week**, ultimately colonizing 17 patients, of whom 11 died — six from infection and five from their underlying disease while infected [emphasis added].

An August 22, 2012 story about the outbreak in *The New York Times* reported the following:[4]

> At first, the hospital was confident that it could contain **bacteria that could easily kill other patients whose immune systems were weakened by disease**, said Dr. Tara Palmore, deputy epidemiologist at the Clinical Center [emphasis added]. The doctors knew **the bacteria would be almost impossible to stop** once they got into patients' bloodstreams [emphasis added].
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> "It really is **the proverbial superbug**," Dr. Palmore said [emphasis added].
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> So the hospital used an approach called enhanced contact isolation. The patient was kept in a single room in intensive care. Everyone who entered had to wear a mask and gloves. Every piece of equipment that touched the patient had to be disinfected. And items like blood pressure cuffs and stethoscopes that could not be disinfected were thrown away.

Likewise, a related story in *The Washington Post* on the same day noted the following:[5]

> As a **deadly infection, untreatable by nearly every antibiotic**, spread through the National Institutes of Health's Clinical Center last year, the **staff resorted to extreme measures** [emphasis added]. They built a wall to isolate patients, gassed rooms with vaporized disinfectant and even ripped out plumbing. They eventually used rectal swabs to test every patient in the 234-bed hospital.
>
> Still, for six months, as physicians fought to save the infected, the bacteria spread, eventually reaching 17 gravely ill patients. Eleven died, six from bloodstream superbug infections. …
>
> This was "**the proverbial superbug that we've all worried about for a long time**," said Tara Palmore, an infection control specialist at the Bethesda hospital [emphasis added]. …
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> After the [first] patient [with the superbug infection] was discharged the next month, Palmore and her staff thought these measures had worked. There were no signs that the bacteria had spread.
>
> But a few weeks later, Palmore **was "horrified," she said, when a second patient tested positive for the bacteria** [emphasis added]. A third and fourth soon followed. Those three patients died as **the bacteria grew impervious to every known antibiotic — even experimental new drugs** [emphasis added]. …

> With genetic evidence of a single-source outbreak, in mid-August [2011] the Palmore-led staff quickly rolled out strict new measures. They built a wall in the [intensive care unit (ICU)] and moved the Klebsiella-positive patients into a new, six-bed unit. Blood pressure cuffs and other reusable gear were tossed after one use.
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> The hospital hired monitors to ensure doctors and nurses were donning gowns, gloves and masks and scrubbing their hands. If monitors fell asleep or otherwise shirked, Palmore fired them and found new ones. **At one point, nine monitors were on duty** [emphasis added].
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> "It was an enormous effort on a daily basis," Palmore said. …
>
> "This is the moment that my professors talked about when we would run out of antibiotics," said Palmore, recalling 20-year-old medical school lectures that warned of **a new era of nasty superbugs** [emphasis added].
>
> The strict infection-control measures eventually paid off. The last new case was found in January, and no new cases have occurred since, she said. **However, two Klebsiella-positive patients remain at the hospital** [emphasis added].
>
> "I would say we controlled the outbreak, **but we're in constant danger of transmission from patients still here**," she said. "**We're not out of the woods yet**" [emphasis added].

Questions:

(a) Why did the NIH fail to publicly disclose this deadly multi-drug-resistant Klebsiella outbreak for one year after having evidence in August 2011 that this was a single-source outbreak and after new, linked superbug infections began occurring at a rate of approximately one per week?

According to *The Washington Post* story referenced above, an NIH spokeswoman noted that reporting such infections is not mandated by the Centers for Disease Control and Prevention (CDC) and downplayed such outbreaks as being "too common to be newsworthy." Such explanations for the failure to report and publicly disclose this outbreak are wholly inadequate.

By not alerting the public sooner, the NIH denied patients considering inpatient care at its Clinical Center the opportunity to weigh the risk of exposure to the Klebsiella superbug against the benefits of being hospitalized there and to consider seeking care elsewhere.

(b) Has the NIH now established a formal policy for publicly disclosing such dangerous infectious disease outbreaks in a timely matter in the future?

(2) In an August 23, 2012 story discussing concerns raised about the failure of the NIH to promptly disclose the deadly Klebsiella superbug outbreak at its Clinical Center to the public, *The Washington Post* reported the following:[6]

> The top staffers at the 234-bed research hospital were so concerned about the outbreak that **they began turning away surgery patients to protect them against infection** [emphasis added].
>
> "There were patients we advised not to come into the hospital," said Henry Masur, chief of the hospital's Critical Care Medicine Department. "We decided not to do elective surgery for a period of time if the patient might have to come into the intensive care unit," the epicenter of the outbreak. …
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> As the outbreak progressed, the hospital "became more and more stringent about who should come in and who should not," Masur said. "I don't think it was ever an all-or-none" situation.
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> Defending the way the hospital handled the situation, Masur said hospital physicians were encouraged to inform their patients about the risk of infection. "Our approach was to make sure all providers had this information, and **all providers could discuss with their patients how it might affect their decision whether to get care** [emphasis added]." …
>
> NIH's Masur said that few patients were at risk. "**For many patients going into the hospital, this organism was irrelevant,**" he said [emphasis added]. "If you come in for mental health, if you come in for an outpatient provider, if you're not terribly sick, this organism posed no risk to you."

Questions:

(a) The above comments by Dr. Masur suggest that the decision to inform patients already admitted or to be admitted to the NIH's Clinical Center during the outbreak was made only at the discretion of the physicians caring for the patients.

Once the NIH recognized the seriousness of the outbreak, why didn't it mandate that all patients already admitted or being considered for admission to the Clinical Center, particularly those who would possibly need care in the ICU because of their underlying disease or potential complications related to their surgical or medical care, be informed of the risk of exposure to the deadly Klebsiella superbug?

(b) Has the NIH now established a formal policy mandating disclosure of such dangerous infectious disease outbreaks to patients admitted to the Clinical Center who are at risk of exposure to the infectious agent?

(c) Given Dr. Palmore's statement in the August 22 story in *The Washington Post* that there is a "constant danger of transmission from patients [infected with the Klebsiella superbug] still [at the Clinical Center]," are all patients considered for

admission to the hospital now being advised of the risk of exposure to this superbug?

(d) In their article in *Science Translational Medicine*, the NIH researchers reported that rectal screening for the Klebsiella superbug was performed three times in the entire Clinical Center hospital patient population between August 2011 and January 2012.[7] Furthermore, transmission of the Klebsiella superbug occurred outside the Clinical Center ICU in five of 17 patients (29 percent), and one of these five patients developed a bloodstream infection with the Klebsiella superbug and died (reportedly from his underlying disease).[8]

Given the urgent need to screen all Clinical Center inpatients on three separate occasions and the fact that transmission of the Klebsiella superbug infection was occurring outside the ICU setting, what was the basis for Dr. Masur's assertion to the media that "For many patients going into the hospital, this organism was irrelevant"?

(3) In a story discussing concerns raised about the failure of the NIH to promptly report the deadly Klebsiella superbug outbreak at its Clinical Center to local and state public health authorities, *The Washington Post* reported the following:[9]

> As a federal facility, the NIH hospital is not licensed by Maryland **and is not required to report hospital-borne infections to the state** [emphasis added].
>
> State epidemiologist David Blythe said NIH officials contacted the health department in December — **four months after the outbreak began** — to ask for advice on stopping the superbug [emphasis added].
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> The NIH's Clinical Center is unique. Every patient is enrolled in a government study, there is no emergency room, and no one goes there to have a baby or get an appendix removed. The patients tend to be the sickest of the sick — those with no other options. **Those were the patients — those with weakened immune systems — who were at highest risk for contracting the superbug**.
>
> Since 2003, **26 states, including Maryland, have passed laws requiring that hospitals report hospital-borne infections** [emphasis added]. The federal health-care law requires such reporting nationwide, although that provision is still being put into effect. Facilities that show rates of hospital-acquired infection higher than the national average stand to lose 1 percent of their Medicare and Medicaid funding.
>
> **The CDC has long pushed hospitals to disclose such infections**, said Mike Bell, deputy director of the center's division of health-care quality promotion [emphasis added]. "Transparency drives change," he said. "When people can see where infections are occurring, it helps them make good decisions."

Question:

The NIH, being the most prominent agency within the U.S. Public Health Service and being staffed by hundreds of officers in the U.S. Public Health Service Commissioned Corps, certainly must recognize the importance of having healthcare facilities promptly report outbreaks of life-threatening infectious disease outbreaks, such as the Klebsiella superbug outbreak at the Clinical Center, to state and local public health agencies. Why did the NIH fail to promptly notify the Maryland health department and Montgomery County public health officials about the Klebsiella superbug outbreak?

Asserting that its status as a federal facility not licensed in Maryland makes it exempt from such reporting is not an acceptable excuse for NIH's failure to report such outbreaks in a timely manner to state and local public health agencies.

(4) *The Washington Post* reported that hours before the first patient with the multi-drug-resistant Klebsiella infection arrived at the NIH from New York City, "NIH nurses noted something startling in her chart: She was carrying an antibiotic-resistant infection."[10]

Questions:

(a) Why was the NIH reviewing the chart of the first patient with the Klebsiella superbug startled to learn when reviewing the patient's medical record before admission?

(b) Were the healthcare providers responsible for making the decision to admit the first patient to the NIH aware that she had been diagnosed with the Klebsiella superbug infection before accepting her for admission to the NIH Clinical Center? If not, why not? If so, why was this information not promptly communicated to the NIH nursing staff?

(5) In their article in *Science Translational Medicine,* the NIH researchers noted that five of the patients found to be infected with the Klebsiella superbug infection died from their underlying disease.[11] However, two of these patients had developed bloodstream infections with the superbug.

Question:

What is the evidence that the bloodstream infection with the Klebsiella superbug did not contribute to the deaths of these two patients? This question is important because the NIH may desire to downplay the number of deaths that were caused by the outbreak of this superbug infection.

(6) In their article in *Science Translational Medicine,* the NIH researchers reported that rectal screening for the Klebsiella superbug was performed on patients in high risk wards as cases were detected and three times in the entire Clinical Center hospital patient population between August 2011 and January 2012.[12]

Questions:

(a) Were all patients who underwent this rectal surveillance informed of the reasons for the surveillance and their potential exposure to the specific life-threatening bacteria for which the surveillance was being performed?

(b) Is such surveillance ongoing, and if so, are all patients now being informed of the reasons for the surveillance and their potential exposure to the specific life-threatening bacteria for which the surveillance is being performed?

Public Citizen recommends that you appoint an independent entity, such as your department's Office of Inspector General, to review the NIH's handling of information related to the Klebsiella superbug outbreak and the research agency's failure to promptly inform all potentially affected patients, public health authorities, and the public at large. The public deserves complete and expeditious answers to the troubling questions posed above.

Thank you for your attention to this important public health matter.

Sincerely,

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cc: Daniel R. Levinson, J.D., LL.M., Inspector General, U.S. Department of Health and Human Services
Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health

[1] National Institutes of Health. NIH uses genome sequencing to help quell bacterial outbreak in Clinical Center. NIH News. August 22, 2012. Available at http://www.nih.gov/news/health/aug2012/nhgri-22.htm. Accessed September 4, 2012.
[2] Snitkin ES, Zelazny AM, Thomas PJ, et al. Tracking a hospital outbreak of carbapenem-resistant *Klebsiella pneumoniae* with whole-genome sequencing. Sci Transl Med. 2012 Aug 22;4(148):148ra116.
[3] National Institutes of Health. NIH uses genome sequencing to help quell bacterial outbreak in Clinical Center. NIH News. August 22, 2012. Available at http://www.nih.gov/news/health/aug2012/nhgri-22.htm. Accessed September 4, 2012.
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[5] Vastag B. 'Superbug' stalked NIH hospital last year, killing six. The Washington Post. August 22, 2012. Available at http://www.washingtonpost.com/national/health-science/superbug-stalked-nih-hospital-last-year-killing-six/2012/08/22/5be18b1a-ec66-11e1-9ddc-340d5efb1e9c_story.html?hpid=z6. Accessed September 4, 2012.
[6] Vastag B. NIH should have notified it of superbug outbreak, Montgomery County official says. The Washington Post. August 23, 2012. Available at http://www.washingtonpost.com/national/health-science/nih-should-have-notified-it-of-superbug-outbreak-montgomery-county-official-says/2012/08/23/838ddcdc-ed50-11e1-9ddc-340d5efb1e9c_story.html?hpid=z5. Accessed September 4, 2012.
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[8] Ibid.
[9] Vastag B. NIH should have notified it of superbug outbreak, Montgomery County official says. The Washington Post. August 23, 2012. Available at http://www.washingtonpost.com/national/health-science/nih-should-have-notified-it-of-superbug-outbreak-montgomery-county-official-says/2012/08/23/838ddcdc-ed50-11e1-9ddc-340d5efb1e9c_story.html?hpid=z5. Accessed September 4, 2012.
[10] Vastag B. 'Superbug' stalked NIH hospital last year, killing six. The Washington Post. August 22, 2012. Available at http://www.washingtonpost.com/national/health-science/superbug-stalked-nih-hospital-last-year-killing-six/2012/08/22/5be18b1a-ec66-11e1-9ddc-340d5efb1e9c_story.html?hpid=z6. Accessed September 4, 2012.
[11] Snitkin ES, Zelazny AM, Thomas PJ, et al. Tracking a hospital outbreak of carbapenem-resistant *Klebsiella pneumoniae* with whole-genome sequencing. Sci Transl Med. 2012 Aug 22;4(148):148ra116.
[12] Ibid.